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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,436	12/18/2001	Jonathan Clark	179-54	1671

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,436

Applicant(s)

CLARK ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3 and 10-15 in Paper No. 9 are acknowledged. The traversal is on the ground(s) that an indication of the class and subclass of the subject matter has not been identified in each group to provide a basis for restriction. Because there is no such class/subclass indication hence, applicants assumed that the subject matter of Groups I-III is classified in the same class/subclass. This being the case, applicants state that the restriction requirement should be withdrawn and all claims in the application examined. This is not found persuasive because restriction is not based solely on the class/subclass to which each of the subject matter belongs. Rather, because each of the subject matter is distinct and divergent. A prior art reference anticipating one subject matter would not render obvious the other subject matters. Furthermore, the searches are not solely directed to U.S. Patents but to non-patent literature search, as well. U.S. Patent search is not co-extensive with non-patent literature search.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 4-9 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **with** traverse in Paper No. 9.

Applicants' election of the species, peptide, is noted.

Status of Claims

Claims 1-16 are pending in the application.

Claims 4-9 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-3 and 10-15 are under examination.

Information Disclosure Statement

The listing of references in the specification, pages 23-25, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration by inventor, Jonathan Clark on his residence and Post Office addresses. See 37 CFR 1.52(c).

Specification

Abstract

The abstract of the disclosure is objected to because it is too long and uses the PCT abstract. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of **50 to 150** words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Essential Material

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to W0 97/42216 is improper because it discloses the essential step of deconvolution of combinatorial libraries.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enzyme with specific modification of the residue as Tyr, Ser or Thr, does not reasonably provide enablement for any type of modification of any kind of residue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of enabling disclosure provided in the specification is not commensurate in scope with the broadly recited claims. The claims encompass a broad number of infinite compounds of unspecified structures and/or other undefined variables. The specification, specifically the Examples, which describes the actual experiments done, exemplifies specific components, conditions and other definite variables for the method. There is no reasonable assurance provided in the specification that the specific embodiments provided in the specification can be applied to the broad scope of the claims. The broadly claim method of unspecified conditions encompassing

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infinite compounds lead to unpredictable determination of the undefined factors. For example, the kind of amino acids in the library, the type of amino acid that can be modified, the type of modifications, the residues that can be fixed and those that are invariant, the conditions which allow for modifications and/or binding, in situ separation and identification of the other numerous unpredictable factors not immediately apparent from the specification. Because of the numerous unpredictable factors an artisan have to determine and because of the limited direction or guidance provided in the specification, the claimed method is merely an invitation to experiment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). In claim 1 the term "preferably" is indefinite.

B). Claim 11 is indefinite because of the incorporation of the foreign patent WO 97/42216. It is not clear as to the

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content or portion of the World Patent that is included or excluded by the claim.

C). Claim 12 is indefinite and broadens the base claim in the recitation of "may optionally include at any place of the formula one or more invariant residues". While the lower limit is provided there is no upper limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 10-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Quibell et al (WO97/42216).

Quibell et al discloses at page 25, line 1 up to page 68 a method of identifying a motif for a substrate by contacting a degenerate library of a substrate with an enzyme and deconvoluting the degenerate library. See specifically the Examples starting at page 49. Accordingly, the method of

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Quibell, which discloses specific steps for such determination with specific enzymes fully meets the broad claimed invention.

Applicants cannot rely upon the foreign priority filing date papers because the subject matter of the instant application is not described in the foreign priority papers.

Claims 1-3 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al (WO 96/23813). [As best as the broad claimed invention can be interpreted].

Patel discloses at page 28, line 14 up to page 114, line 256, the Examples, a method of identifying a motif of a peptide substrate from a degenerate library containing a modifiable residue and an invariant residue by contacting said library with a specific enzyme. See specifically the examples, which show the different modifications of different residues, the construction of the library at page 89, Example 32. See also the drawing figures, which show the method step by step. The deconvolution method is disclosed at page 114, Example 44. Accordingly, the specific method steps of Patel fully meet the broad claimed method.

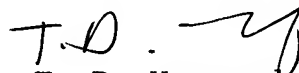
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 25, 2003